

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The updated searches of the art did not reasonably teach or suggest the claimed invention directed to a method of treating xerostomia comprising administering a sialogogue composition comprising polyglutamic acid [PGA] having an average molecular weight of 10,000 to 5,000,000 Daltons or a salt thereof, in the specific carrier forms.

Additionally, Applicant's arguments over the prior art combination of record, particularly the new primary reference (MSG as opposed to 10-50K Dalton PGA) have been fully considered, and are deemed persuasive that:

A sialogogue is a composition which promotes salivary secretion. Salivary secretion can be stimulated in multiple ways, one of which is in response to a good taste.

The Examiner asserts that "[p]olyglutamic acid of the salt form of MSG is simply > 1 molecule of the same. Thus, if a single molecule works as a sialogogue, the skilled artisan would know that more than one molecule would also (e.g., any form of polyglutamic acid)" (Office Action, page 6). **Applicants respectfully submit that MSG and polyglutamic acid are significantly different in multiple ways.**

First, MSG and polyglutamic acid have a different structure. The effect of these different structures has been completely ignored by the Examiner in asserting obviousness. By their size alone, MSG and polyglutamic acid would be expected to have **significantly different properties**. In particular, claims 20, 21, and 28 all recite that **the average molecular weight is between 10,000 and 5,000,000 Daltons. The interaction of these molecules with receptors and/or other chemicals *in vitro* and *in vivo* would be expected to be different from that of a small molecule such as MSG.**

Also, the two compositions **act as sialogogues through different mechanisms**. MSG is known to have a **delicious taste**. Salivary secretion can be stimulated by **pleasant tastes**.

However, **polyglutamic acid has no taste**, as described in the Specification at page 2, line 22, and page 10, Table 22. Accordingly, the mechanism by which polyglutamic acid acts as a sialogogue is different than that of MSG. For this reason, one of skill in the art would not find the use of polyglutamic acid as a sialogogue obvious in view of the disclosure of the use of MSG as a sialogogue. **Stated another way, when the prior art understood that MSG acted as a sialogogue, a person skilled in the art with that knowledge would not be motivated to use a tasteless compound (polyglutamic acid) as a sialogogue.**

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In addition, the fact that polyglutamic acid or its salt acts as a sialogogue (*i.e.*, promotes salivary secretion or a moisturizing effect) is not disclosed in Tanimoto, Yalpani, and Napolitano. Thus, the combination of the prior art does not teach every element of the claimed method as it fails to teach that polyglutamic acid promotes salivary secretion. Applicants request that the rejection be withdrawn.

Furthermore, it is an **unexpected benefit that the claimed composition is tasteless**, especially when MSG has such a distinctive taste. The Specification points out that the use of **many sialogogues is limited by their taste** (Specification, page 2, line 5-6), thereby distinguishing the presently claimed invention from sialogogues that generate saliva secretion by taste. Applicants submit that the fact that polyglutamic acid is tasteless is an unexpected result which overcomes any showing of *prima facie* obviousness that may have been established. For this additional reason, Applicants request that the rejection be withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 10/25/2010

/Maury Audet/
Primary Examiner, Art Unit 1654